Re-evaluation Note REV2017-19

Special Review of Chlorthal-dimethyl: Proposed Decision for Consultation

(publié aussi en français)

13 July 2017

This document is published by the Health Canada Pest Management Regulatory Agency. For further information, please contact:

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Canada

ISSN: 1925-0630 (print)
1925-0649 (online)

Catalogue number: H113-5/2017-19E (print version)
H113-5/2017-19E-PDF (PDF version)

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1.0 Introduction

Pursuant to subsection 17(2) of the *Pest Control Products Act*, the Pest Management Regulatory Agency (PMRA) has initiated a special review of pest control products containing chlorthal-dimethyl based on the decision taken by the European Commission in 2009. The initiation of the special review under the *Pest Control Products Act* was announced in December 2013, and the aspect of concern was related to the leaching of a chlorthal-dimethyl transformation product into groundwater.

Pursuant to subsection 18(4) of the *Pest Control Products Act*, the PMRA has evaluated the aspect of concern that prompted the special review of pest control products containing chlorthal-dimethyl.

Uses of Chlorthal-dimethyl in Canada

Chlorthal-dimethyl is a pre-emergent herbicide used to control broadleaf weeds and grasses. It is formulated as a wettable powder that is used on turf, ornamentals, fruits, and vegetables. Chlorthal-dimethyl is applied using ground application equipment only, with no more than two applications per year. In Canada, chlorthal -dimethyl underwent re-evaluation in 2008. Appendix I lists all chlorthal-dimethyl pest control products that are currently registered under the authority of the *Pest Control Products Act*. Currently, there is one technical product, one manufacturing concentrate, and one commercial end-use product containing chlorthal-dimethyl registered in Canada, and all registered pest control products containing chlorthal-dimethyl are considered in this Special Review.

2.0 Aspects of the Pest Control Product that Prompted the Special Review

The European Commission completed a re-evaluation of chlorthal-dimethyl in 2009 as per Directive 91/414/EEC. Their final decision concluded that *"during the evaluation of this active substance it was found that its metabolite monomethyltetrachlororoterephthalate (MPA) leaches to groundwater. On the basis of the information available, it cannot be concluded that it may be expected that the plant protection products containing that active substance fulfil the conditions provided for in Article 5(1) of Directive 91/414/EEC, in particular as regards toxicological significance of that metabolite"*.

Based on the review of the European Commission decision, the PMRA identified the following aspect of concern that prompted the special review:

- Leaching of the transformation product MPA to groundwater

3.0 PMRA Evaluation of the Aspects of the Pest Control Product that Prompted the Special Review

Following the initiation of the special review of chlorthal-dimethyl, the PMRA requested information relevant to the aspect of concern in accordance with subsection 18(2) of the *Pest Control Products Act*. No information related to the aspect of concern was received.

In order to evaluate the potential for the transformation product MPA to leach into groundwater, the PMRA has considered currently available relevant scientific information (for example, environmental fate information from laboratory and field studies, available groundwater monitoring data, groundwater modelling, United States Environmental Protection Agency (USEPA) Registration Review).

As of 27 April 2017, there is no information related to the aspect of concern in the PMRA incident report database.

Environmental Fate and Behaviour of MPA

Chlorthal-dimethyl is stable to hydrolysis and photolysis, and the primary route of transformation for the parent is aerobic biotransformation. MPA (DT_{50} = 1-14 days) is a short-lived intermediate, transitory product in the biotransformation of chlorthal-dimethyl to tetrachloroterephthalic acid (TPA). Indeed, in aerobic soil biotransformation studies, MPA only reached a maximum of 16% of the applied radioactivity. In anaerobic soil biotransformation studies, MPA was less than 10% of the applied radioactivity. The parent chlorthal-dimethyl is sparingly soluble in water and only slightly mobile in soil. However, MPA is soluble in water (18.26 mg/L), and, based on K_{oc} values (16-44 mL/g), it is highly mobile in soil and has the potential to leach into groundwater (USEPA,2011).

The existing chlorthal-dimethyl label includes standard advisory label statements to minimize the potential for leaching to groundwater.

MPA Levels in Groundwater

The potential for leaching of MPA to groundwater under Canadian use conditions was assessed using groundwater modelling (EFED PRZM 3.1.22 model). For the purpose of the modelling, it was conservatively assumed that 100% of the chlorthal-dimethyl applied would convert to MPA. All scenarios were run using 50-year weather data, and calculations were based on the maximum yearly application rate of 17.450 kg a.i./ha. The Level 1 modelled estimated environmental concentration (EEC) for the combined residues of chlorthal-dimethyl + MPA was 55 µg a.i./L.

In addition to modelling, available groundwater monitoring data from both Canada and the United States were reviewed by the PMRA to assess the potential leaching of MPA into groundwater. There were no available Canadian monitoring data specific for the transformation product MPA in groundwater; nonetheless, monitoring data were available from the American Monitoring in the United States groundwater was reported as combined residues of MPA and TPA: the maximum reported concentration in well water from California was 15 µg/L. In

addition, a report from the USEPA presents occurrence data for chlorthal and its transformation products in drinking water from public water systems (PWS) sampled as part of the first Unregulated Contaminant Monitoring Regulation (UCMR 1) program. Data ranging from approximately 2001 to 2006 were summarized from a total of 797 small PWSs (systems serving 10,000 people or fewer) and 3,079 large PWSs (systems serving more than 10,000 people). The PWSs were sourced by surface water as well as groundwater (small PWSs: 590 by groundwater, 207 by surface water; large PWSs: 1,389 by groundwater, 1,690 by surface water). Reported as combined residues of chlorthal-dimethyl, MPA, and TPA, the 99th centile concentration of all samples ranged from less than 1.0 µg/L (reporting limit) for large public water systems to 1.3 µg/L for small public water systems.

The level 1 EEC modelled for chlorthal-dimethyl combined with MPA in groundwater was 55 µg/L. Results from monitoring data relative to the aspect of concern are below 55 µg/L.

Drinking Water Risk Assessment:

In addition to assessing the leaching potential of MPA to groundwater, the PMRA conducted a dietary risk assessment to determine whether MPA in Canadian groundwater presents a risk of concern. For the purpose of the dietary risk assessment, MPA was considered to be equivalent in toxicity to the parent, chlorthal-dimethyl.

MPA and chlorthal-dimethyl were evaluated together in the dietary assessment. No appropriate toxicological endpoint attributable to a single dose for the general population (including children and infants) was identified, therefore, no acute dietary risk assessment was required. For chronic non-cancer dietary exposure, the acceptable daily intake (ADI) for chlorthal-dimethyl + MPA was determined to be 0.01 mg/kg bw/day, based on a no observed adverse effect level (NOAEL) of 1 mg/kg bw/day from a combined chronic/carcinogenicity study in rats and an uncertainty factor of 100. The uncertainty factor of 100-fold is considered protective of any potential developmental or reproductive toxicity, as there were no residual uncertainties with respect to the completeness of the data and / or the potential toxicity to infants and children. For cancer dietary exposure, the cancer potency factor (q_1^*) for chlorthal-dimethyl + MPA was determined to be 0.0015 (mg/kg bw/day)$^{-1}$ based on 3 combined types of liver tumours observed in female rats (Canada, 2008).

Chronic exposure to chlorthal-dimethyl + MPA from combined food and drinking water (EEC value = 55 µg a.i./L) is not of concern. Specifically, a range from 9.2% to 47.2% of the ADI was obtained for all population subgroups. Infants were the highest exposed population subgroup.

The lifetime cancer risk from exposure to chlorthal-dimethyl + MPA in food and drinking water was estimated to be 1.6×10^{-6} for the general population. Considering the conservative assumptions for drinking water and food intake (for example, the use of maximum application rates and maximum yearly application frequency to estimate MPA groundwater concentrations; the use of field trial data to estimate chlorthal-dimethyl and MPA residues in food commodities; and the fact that the EEC value used in the risk assessment was higher than levels detected in

Canadian or American groundwater or drinking water), it is expected that human health risks from the leaching of MPA to groundwater are not of concern.

The European Commission adopted a level of 0.1 µg/L as the maximum acceptable concentration in groundwater for individual pesticides in 1998. The 0.1 µg/L threshold is a legislated, rather than scientifically risk-based value that applies to all pesticides regardless of their toxicity to humans. Conversely, the PMRA follows a scientific approach in determining the risk to human health from pesticides in drinking water. This approach takes into consideration both the estimated level in drinking water sources (exposure) and the toxicity of the pesticide.

Based on the above assessment, the PMRA concludes that there are no risks of concern from MPA in Canadian groundwater under the current conditions of use. Moreover, the current label contains statements to minimize the potential leaching to groundwater. To provide further clarity, the PMRA is proposing to add a maximum yearly application rate (17.450 kg a.i./ha) statement to the current label (Appendix II).

4.0 Proposed Special Review Decision for Chlorthal-dimethyl

Evaluation of available relevant scientific information related to the aspect of concern (leaching of MPA to groundwater) indicated that registered pest control products containing chlorthal-dimethyl do not pose unacceptable risks to human health and the environment, taking into account the current conditions of use. On this basis and under the authority of the *Pest Control Products Act*, the PMRA is proposing to confirm the current registration of pest control products containing chlorthal-dimethyl for sale and use in Canada with the proposed label amendment. This proposal affects all registered products containing chlorthal-dimethyl in Canada.

This proposed special review decision is a consultation document.[1] The PMRA will accept written comments on this proposal up to 45 days from the date of publication of this document. Please forward all comments to Publications (please see contact information on the cover page of this document).

5.0 Next Steps

Before making a special review decision on chlorthal-dimethyl, the PMRA will consider any comments received from the public in response to this consultation document. A science-based approach will be applied in making a final decision on simazine. The PMRA will then publish a special review decision document, which will include the decision, the reasons for it, a summary of the comments received on the proposed decision and the PMRA's response to these comments.

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1 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

Appendix I Registered Products Containing Chlorthal-dimethyl as of 27 April 2017

Registration Number	Marketing Class	Registrant	Product Name
8963	Commercial	AMVAC Chemical Corporation	Dacthal W-75 Herbicide
20850	Technical		Dacthal Technical Herbicide
22602	Manufacturing Concentrate		90% Dimethyl-T Manufacturing Concentrate

Appendix II Proposed Label Amendemnts for Chlorthal-dimethyl

1) The label(s) of Chlorthal-dimethyl end-use products must be amended to include the following statements:

   Add to **DIRECTIONS FOR USE**:

   "The maximum yearly application rate is not to exceed 17.450 kg a.i./ha"

References

I) Information Considered in the Special Review not Supplied by Registrant

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